

REMARKS

The above amendments and these remarks are responsive to the Office action dated March 11, 2004. Claims 28-30, 33-41, and 83-89 are pending in the application. In the Office action, the Examiner objected to applicants' Information Disclosure Statements, and rejected all of the pending claims under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,524,790 to Kopf-Sill et al ("Kopf-Sill"). Applicants traverse these rejections. In particular, applicants do not believe that Kopf-Sill or any other reference teaches or suggests each and every limitation in the rejected claims, such as a "mass label," as required for anticipation. Thus, in view of the above amendments, and the following remarks, applicants respectfully request reconsideration of the application under 37 C.F.R. § 1.111 and allowance of the pending claims.

I. Information Disclosure Statement

The Examiner stated that three Information Disclosure Statements—filed on (1) January 6, 2000, (2) September 13, 2002, and (3) June 23, 2003—failed to comply with 37 C.F.R. § 1.98(a)(1) because they did not include a list of all patents, publications, or other information submitted for consideration. Applicants believe that there must be some confusion regarding the Information Disclosure Statements filed in the application. In particular, applicants have filed only a single Information Disclosure Statement in this application, on September 21, 2001. This Information Disclosure Statements did include the required list, namely, PTO-1449 forms, as well as copies of all listed references. Nevertheless, to facilitate review of the submitted references, and to save the Examiner the inconvenience of searching for any missing materials, applicants are resubmitting copies of the previously submitted materials. Applicants

respectfully request that the references listed in the resubmitted form(s) be expressly considered during prosecution of this application, and that these references be made of record herein and appear among the "references cited" on any patents issuing herefrom. Applicants invite the Examiner to telephone the undersigned attorney of record regarding any remaining issues that might arise relating to Information Disclosure Statements.

II. Claim Rejections – 35 USC § 102

The Examiner rejected all of the pending claims under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,524,790 to Kopf-Sill et al ("Kopf-Sill"). Applicants traverse these rejections. In particular, applicants do not believe that Kopf-Sill or any other reference teaches or suggests each and every limitation in the rejected claims, as required for anticipation. For example, as described below, Kopf-Sill fails to teach or suggest a "mass label," as required by all of the pending claims.

A. Brief Overview of Pending Claims

The application currently includes one independent claim (claim 83) and eighteen dependent claims (claims 28-30, 33-41, and 84-89).

The independent claim is directed to a kit for detecting the presence and/or activity of an analyte in a sample:

83. (Amended) A kit for detecting the presence and/or activity of an analyte in a sample, the kit comprising:

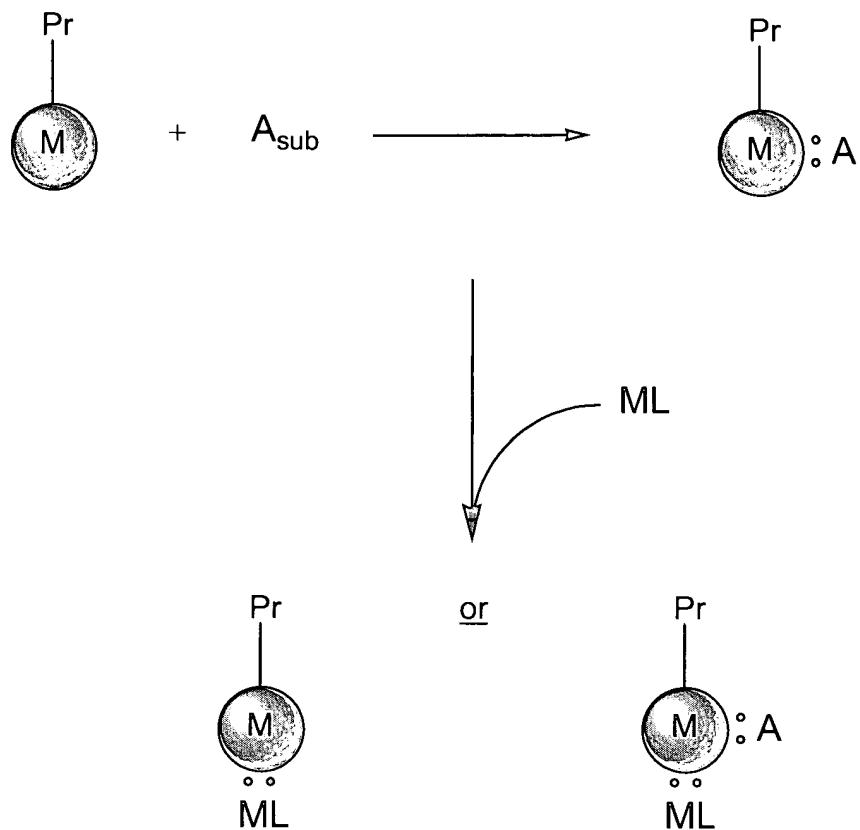
a probe bound to a member, where the member is a compound that specifically binds to the analyte, or is a substrate for the analyte; and

a particulate mass label capable of specifically binding to one of the member[[,]] and the complex formed by binding of the member to the analyte, or one of the member and the product of the action of the analyte on the member;

wherein a measurable property of the probe is sensitive to the size of the complex formed by binding of the mass label, probe, and the member, member-analyte complex, or member product.

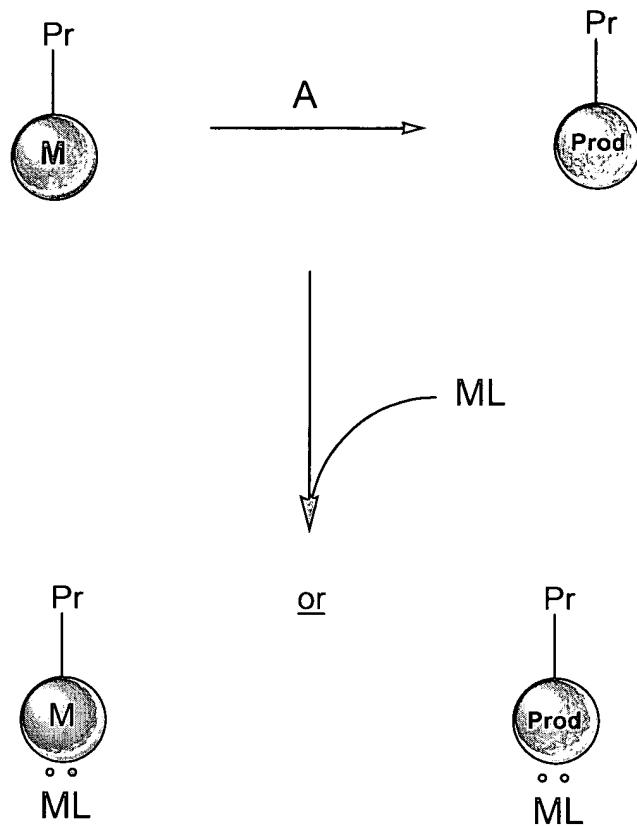
The kit includes (1) a "probe bound to a member," and (2) a "particulate mass label." The member is a compound that (1) specifically binds to the analyte, or (2) is a substrate for the analyte. The particulate mass label is capable of specifically binding to (1) one of the member and the complex formed by binding of the member to the analyte, or (2) one of the member and the product of the action of the analyte on the member. Finally, a measurable property of the probe is sensitive to the size of the complex formed by binding of the mass label, probe, and the member, member-analyte complex, or member product.

The claimed kit can be used, among other applications, to detect the presence and/or activity of an analyte in reactions in which a member binds specifically to the analyte:



Here, a probe ("Pr") bound to a member ("M") specifically binds to an analyte ("A") to form a complex, and a mass label ("ML") specifically binds to one of the member and the complex formed by binding of the member to the analyte. In addition, a measurable property of the probe is sensitive to the size of the complex formed by binding of the mass label, probe, and member (left) or the mass label, probe, and member-analyte complex (right). Thus, in this reaction, the kit can detect the binding reaction by allowing measurement of a decrease in uncomplexed member or an increase in complexed member, depending on the binding preference of the mass label between uncomplexed and complexed member.

The claimed kit also can be used, among other applications, to detect the presence and/or activity of an analyte in reactions in which a member is a substrate for an analyte:



Here, a probe ("Pr") bound to a member ("M") is a substrate for an analyte ("A"), and a mass label ("ML") specifically binds to one of the member and a product ("Prod") of the action of the analyte on the member. In addition, a measurable property of the probe is sensitive to the size of the complex formed by binding of the mass label, probe, and member (left) or the mass label, probe, and member product (right). Thus, in this assay, the kit can detect the action of the analyte by allowing measurement of a decrease in unreacted member or an increase in reacted member (i.e., member product), depending on the binding preference of the mass label between unreacted and reacted member.

The dependent claims depend from and further limit the independent claim. These claims add additional limitations, such as the nature of the measurable property (e.g., fluorescence polarization), the relationship between the photoluminescence lifetime of the probe and the rotational correlation time of various participants (e.g., the probe, with and without binding to the mass label) in an assay, and so on.

B. The Pending Claims are Not Anticipated by Kopf-Sill

The Examiner rejected the pending claims as anticipated under 35 U.S.C. § 102(e) by Kopf-Sill. A reference anticipates a claim only if the reference includes each and every limitation in the claim. Thus, to anticipate the pending claims, Kopf-Sill must disclose, among other limitations, kits having a particulate mass label capable of specifically binding to one of a member and a complex formed by binding of the member to an analyte, or one of a member and the product of the action of an analyte on the member. Significantly, Kopf-Sill does not disclose such a mass label. Thus, because it does not disclose each and every limitation in claim 83, or the claims depending therefrom, Kopf-Sill does not anticipate the pending claims.

Kopf-Sill does disclose reactions, including binding reactions and enzyme reactions, as well as methods and compositions for monitoring aspects of these reactions. For example, Kopf-Sill discusses how velocity differences between reactant ("R") and product ("P") can be used to monitor enzyme reactions such as $R \xrightarrow{\text{Enzyme}} P$. See, e.g., Kopf-Sill, claim 1. These velocity differences can be determined by monitoring the position of R and P as a function of time using a marker such as a fluorophore. See, e.g., Kopf-Sill, claim 3. However, Kopf-Sill does not disclose a "particulate mass label," distinct from the probe, that binds specifically to one of R and P. Moreover, Kopf-Sill

does not disclose a “probe” having a measurable property that is sensitive to the size of a complex formed by binding of a mass label and one of *R* and *P*. Instead, Kopf-Sill merely uses a marker, such as a fluorophore, to assay an existing, measurably distinct characteristic of *R* and *P*, without further modification or reaction. In contrast, the claimed kits use an additional moiety—a mass label—that interacts with one of *R* and *P* (in this case) to accentuate or create a measurably distinct characteristic of two species, namely, a member and either a member-analyte complex or a member product.

Kopf-Sill also fails to teach or suggest limitations found in dependent claims that depend from and further limit independent claim 83. For example, claim 89 recites that the measurable property (of the probe) may be measured using fluorescence polarization. The Examiner suggests that this limitation is anticipated by Kopf-Sill, column 28, lines 1-6. However, the Kopf-Sill reference fails to even mention fluorescence polarization. Additionally, the cited portion of Kopf-Sill recites fluorescent dyes (“fluorescein isothiocyanate, texas red, rhodamine, and the like”) having short nanosecond lifetimes that would be highly polarized upon association with most members even in the absence of a mass label to change the effective size of the probe. Similarly, claim 29 recites that photoluminescence lifetime of the probe is greater than the rotational correlation time of the unbound probe and less than the rotational correlation time of the complex formed by binding of the probe, member or member product, and mass label. However, again, the use of short-lifetime fluorescent dyes as pointed to by the Examiner, in the absence of a mass label, would teach away from, rather than anticipate, the claimed limitation.

In conclusion, because it does not disclose each and every limitation in claim 83, or the claims depending therefrom, such as a mass label, Kopf-Sill does not anticipate the pending claims.

III. Claim Amendments

Applicants have amended independent claim 83 to more particularly point out and distinctly claim aspects of the present teachings. These amendments clarify aspects of the binding specificity of the mass label, without narrowing or otherwise further limiting the claim.

IV. Conclusion

Applicants believe that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowance covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

CERTIFICATE OF MAILING

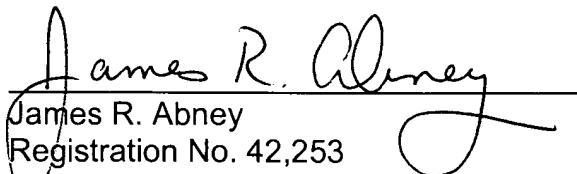
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, to: Mail Stop AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on June 14, 2004.



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Respectfully submitted,

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